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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,276	06/29/2001	Y. Tom Tang	PF-0609 USN	6626

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Incyte Genomics Inc
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EXAMINER
ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,276	TANG ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-45* is/are pending in the application.

4a) Of the above claim(s) *21,22 and 32-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group II (claims 23-31) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the claims not be restricted because applicant contends that the unity of invention standard must be applied to national stage application. Applicant argues that unity of invention exists with respect to dependent claims in the same claim category as independent claims from which they depend. Note that Paper No.6 provided a lack of unity where applicant was informed that the invention lacks unity and is not linked by a special technical feature as the protein of Invention I did not escape the prior art. Thus the application has been properly addressed. Under the PCT rules applicant is entitled to the first product, method of making and using said product. The first product in the application is the protein and the second product is the DNA. Applicant elected to prosecute the Invention of Group II which encompasses the DNA, host cell, vector and method of producing a protein. Here too the requirement under PCT rules have been met in this application. Therefore, the lack of unity is proper and final.

Claim Disposition

2. Claims 1-20 have been canceled. Claims 21-45 have been added. Claims 23-31 are under examination. Claims 21-45 are pending.

Specification

3. The specification is objected to because of the following informalities: The specification is objected to because on page 1 concerning the continuity data does not refer to the application as being a 371.

Correction is required.

Claim Rejections-Utility Rejections Under 35 USC § 101 And 35 USC 112, First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-31 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well established utility. Claims 23-31 are directed to a polynucleotide encoding a polypeptide, vector, host cell and a method of making the polypeptide (bone marrow derived serum proteins). The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well established utility. The specification fails to provide objective evidence of any activity for the encoded proteins. A well established utility is a specific, substantial, and

credible utility that is well known, immediately apparent or implied by the specification's disclosure of the properties of a material. There is no specific disease or specific function that is suggested for the polynucleotides or the encoded polypeptides. It is noted that page 1 of the specification indicates that invention provides new bone marrow derived serum proteins and polynucleotides which are useful in the diagnosis, prevention, and treatment of cancer, immune disorders, infections and vascular disorders, however, no specific association is made or demonstrated. Page 4 of the specification states that methods are provided for treating or preventing a disorder associated with decreased or activity of BMDSP (bone marrow derived serum proteins), said method comprising administering to a subject in need of such treatment an effective amount of a pharmaceutical composition comprising the polypeptide. No real association is made between a specific disorder/disease and the claimed products. What disorder/disease results from a decreased expression or activity of BMDSP, the specification does not disclose specific information. In addition, pages 24-26 state that BMDSP appears to play a role in cancer, immune disorders, vascular disorders and infections. A laundry list of diseases/disorders (page 25) is provided, however, no exemplification is provided, via a working example. Thus, no empirical evidence exists on the record to demonstrate the association as claimed between the claimed BMDSP and the list of diseases/disorders provided.

The specification asserts that the products of the invention can be used (1) as drugs for the treatment or prevention of cancer, immune disorders etc., (2) in diagnosing disease associated with BMDSP and (3) as probes/primers. As for drugs for the treatment or prevention of cancer, immune disorders, etc., this asserted utility is not substantial. The specification does not disclose any particular conditions wherein there is a deficiency, overproduction, or altered form of the claimed polypeptides. The fact

that the polynucleotide can be found in libraries of cells isolated from for example, cancerous tissues or immune system cells would not indicate to one of skill in the art that BMDSP is involved with any of these conditions. Even if it were differentially expressed in cancerous tissues, for example, there is no indication regarding how to develop a drug to treat cancer based on BMDSP, because there is no information disclosed regarding the role BMDSP plays in healthy tissue. Significant further experimentation would be required of the skilled artisan to identify individuals who would benefit from such a drug, and then to determine a best course of treatment. There is no disclosure, for example, of how to assay for improvement or intolerable levels of side effects or dosages of the drug. Since this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

It is asserted that the invention can be used in diagnosing disease associated with BMDSP, this assertion is not substantial. The specification does not disclose any specific diseases associated with altered levels or forms of BMDSP as discussed above. Significant further experimentation would be required of one skilled in the art to identify individuals having such a disease. There is no indicia, for example, of any symptoms associated with such a disease/disorder. As this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. The assertion is made of a use as probes/primers; however, this utility is not specific, as this can be done with any polynucleotide. The examples on pages 40+ do not demonstrate nor describe the claimed invention. A search of the claimed sequences produced references that did not substantiate the asserted utilities, in fact, Alberts et. al. (The Journal of Biological Chemistry, vol. 273, pages 8616-8622, 1998) teach a sequence that is homologous to the claimed SEQ ID

NO: 4, however, the encoded protein is said to be a RhoA effector protein. In view of the foregoing, and absent data/evidence, the claimed invention lack utility. See *Brenner v. Manson*, 383, U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment. See also the Utility Guidelines available at www.uspto.gov.

5. Claims 23-31 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

6. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present invention is directed to an isolated polynucleotide that encodes a polypeptide and fragments thereof and the claims are directed to the same and a naturally occurring polynucleotide that is 90% identical to SEQ ID NOS: 3 and 4. The specification lacks description or exemplification of any activity for the polynucleotides and the encoding polypeptides. Page one of the specification states that the intended use of the claimed products is for diagnosis, treatment, and prevention of cancer, immune, infections etc. The claim is directed to a fragment and do not recite a functional limitation to indicate that the function as asserted for the protein is retained. There is no function associated with polynucleotides

encoding polypeptides having at least 90% identity to SEQ ID NOS: 3 and 4 or biological activity associated with fragments thereof defined. The specification and claims provide no measurable end point to allow one of skill in the art to be able to determine if a polynucleotide that is in possession of another, and having at least 90% identity to SEQ ID NO: 3, for example, falls within the description of the polynucleotides as claimed. For example, if another were in possession of a polynucleotide encoding a polypeptide having at least 90% identity to SEQ ID NO: 3, and this polynucleotide encodes a polypeptide having extraordinary activity, such as three times more ability to treat cancers than that encoded polypeptide disclosed in the instant specification, then this polynucleotide in the possession of another is not described in the instant specification and would not be considered to fall within the limitations of the claims, regardless of the 90% identity limitation. The specification does not describe polynucleotides encoding polypeptides having at least 90% identity to SEQ ID NO: 3 or 4 and do not decrease the activity of BMDSP, for example. The claims must recite a specific, measurable activity such that one can recognize a polynucleotide as that claimed, or a fragment thereof. Therefore, absent adequate written description with regard to a polynucleotide that encodes a polypeptide having at least (90% identity to SEQ ID NOS: 3-4, one of skill in the art would have to engage in undue experimentation to determine if the fragment retained the asserted association as disclosed on page 25 of the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 24 and 28 are indefinite because the claims depend from non-elected claims.

The dependent claims hereto are also included in this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 23 and 31 are rejected under 35 U.S.C. 102(a) over Alberts et al. (The Journal of Biological Chemistry, vol. 273, No. 15, pages 8616-8622, April 10, 1998).

Alberts et al. teach a polynucleotide sequence that is homologous to the sequence contained in SEQ ID NO: 4 of the instant application which encodes SEQ ID NO: 2. The sequence taught by Alberts has 60 contiguous nucleotides which are identical to SEQ ID NO: 4 (claim 31, see the sequence alignment) and teach the encoded protein (claim 23, page 8616 of the reference). As claim 23 is directed to a polynucleotide encoding a protein that is (d) an immunogenic fragment consisting of at least 20 contiguous amino acid residues of an amino acid sequence of SEQ ID NO: 2 (encoded by SEQ ID NO: 4), the limitations of the claims are met by this reference.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:00 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Christopher S.F. Low

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